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June 16, 2005

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

As directed by the FDA Office of Generic Drugs (OGD), ECR Pharmaceuticals (ECR), submits this petition pursuant to 21 CFR 314.122 requesting that the FDA make a determination that it is suitable to submit an ANDA for a product strength (dexamethasone USP, 1.5 mg tablets) whose innovator and manufacturer (Merck) has discontinued the manufacture of this tablet strength.

ACTION REQUESTED

ECR requests the FDA's determination that the discontinuation of the manufacture of Decadron 1.5 mg tablets (dexamethasone USP, 1.5 mg tablets) by its innovator and manufacturer (Merck) was not due to safety and/or effectiveness reasons, and hence it is suitable to submit an ANDA for approval to market this product strength.

STATEMENT OF GROUNDS

It is ECR's understanding that Decadron (dexamethasone USP) 1.5 mg tablet strength was discontinued by its innovator and manufacturer (Merck) due to insufficient sales of this specific strength. Merck continues to manufacture Decadron in 0.5 mg, 0.75 mg, and 4 mg tablet strengths (FDA Application and Product Number Reference N11664). Decadron 1.5 mg tablets was the reference listed drug (RLD) for this product strength for purposes of comparison with a product which may be the subject of an ANDA submission. Withdrawal of Decadron 1.5 mg tablets left this strength without a RLD. The current electronic Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) lists Decadron 0.75 mg tablets as a RLD and the OGD has indicated that this is a suitable RLD substitute for the higher strength RLD tablet, if the Decadron 1.5 mg tablet was not discontinued because of safety and/or effectiveness reasons.

As background, Decadron tablets are heavily substituted with more than 98% of all prescribed product being dispensed as a generic. The Decadron 1.5 mg tablet is one of the least prescribed strengths of dexamethasone. This factor, combined with the high rate of generic substitution, has apparently resulted in Merck's determination that this strength

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was no longer a viable product for the firm to continue to manufacture and market. Par Pharmaceuticals has also discontinued its manufacture of dexamethasone products, apparently for similar economic reasons. This leaves Roxane Laboratories as the only supplier of dexamethasone, USP 1.5 mg tablets, and a 5 fold price increase has occurred for this product strength. It is ECR's desire to complete an appropriate ANDA to return competition to this small market.

ENVIROMENTAL IMPACT

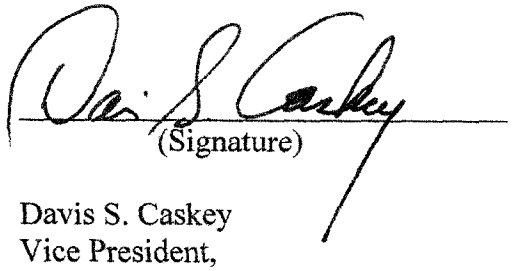
ECR believes that this petition is subject to categorical exclusion under CFR 25.31. The development and subsequent marketing which would result from affirmation of the above requested determination should have no impact on the total dexamethasone market and hence will not increase the use of the active moiety, dexamethasone, USP. Use of this strength may replace equal amounts of other currently available strengths but will not increase the overall use of the drug entity.

ECONOMIC IMPACT

As noted under Statement of Grounds, this product strength is currently available from only one US manufacturer, Roxane Laboratories, and the price of this strength has recently increased five fold. The availability of this strength from another source should yield a more competitive environment and result in more competitive prices.

CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



(Signature)

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